

COVID-19 Vaccine – Moderna (Licensed for use in Canada December 23, 2020)

Product monograph: <https://covid-vaccine.canada.ca/info/pdf/moderna-covid-19-vaccine-pm1.pdf>

	COVID-19 mRNA Vaccine (Frozen Vaccine)
Manufacturer	Moderna
Licensed use	18 years of age and older
Composition/Platform Vaccine Type	<ul style="list-style-type: none"> mRNA (new technology) - nucleoside-modified messenger RNA (modRNA) encoding the viral spike glycoprotein Formulated in lipid nanoparticles (LNPs) No adjuvants, preservatives, antibiotics or human- or animal-derived materials
Indications for use of provincially funded vaccine	This vaccine is being offered in a phased approach. Please follow operational guidelines to assess eligibility.
Dose	0.5 mL
Route	<ul style="list-style-type: none"> Intramuscular injection (IM)
Schedule	<p>2 doses</p> <ul style="list-style-type: none"> ❖ Dose 1: day 0 ❖ Dose 2: 28 days is recommended, but 21-42 days is acceptable. <p>Notes:</p> <ul style="list-style-type: none"> If administration of the second dose is delayed, the second dose should be provided as soon as possible. Currently, no data on a maximum interval between doses or on medium- or long-term efficacy of COVID-19 vaccines are available. In general, regardless of the time between doses, interruption of a vaccine series does not require restarting the series. The initial immune response in elderly people may be less and the waning may be at a greater rate. Since residents of LTC were not included in the clinical trials but they are at highest risk of severe disease outcomes, at this time, administration of the second dose to those in LTCFs and PCHs is to continue as per product monograph spacing. Refer to the Ministry of Health Jan. 12, 2021 <i>COVID-19 Vaccine Immunization Recommendations for Persons with a Current or a Prior History of SARS-CoV-2 Infection</i> letter for further details pertaining to COVID-19 disease occurrence in a client and subsequent immunization.
Contraindications	<ul style="list-style-type: none"> Known severe hypersensitivity to any component of the vaccine. One non-medicinal ingredient in the vaccine known to cause type 1 hypersensitivity reactions is polyethylene glycol (PEG). The potential allergen may be found in bowel preparation products for colonoscopy, laxatives, cough syrup, cosmetics, contact lens care solutions, skin products and some food and drinks. Anaphylaxis to previous dose of COVID-19 mRNA vaccine.
Precautions	<ul style="list-style-type: none"> Individuals receiving anticoagulant therapy or those with a bleeding disorder that would contraindicate intramuscular injection should not be given the vaccine unless the potential benefit clearly outweighs the risk of administration. Administration should be postponed in individuals suffering from acute severe febrile illness. To date, there is also insufficient evidence on the receipt of both a COVID-19 vaccine and any monoclonal antibodies or convalescent plasma for treatment or prevention of non-COVID-19 disease. Therefore, timing of administration and potential interference between these two products are currently unknown and expert clinical opinion should be sought on a case-by-case basis

Immunocompromised and Auto-Immune Conditions	<ul style="list-style-type: none"> At this time, there is an absence of evidence on the use of COVID-19 vaccine in immunocompromised individuals and those with auto-immune conditions. These groups were not included in large enough numbers in the initial trials to provide solid information. COVID-19 vaccine may be offered to individuals in the eligible group who are immunosuppressed due to disease or treatment and those with an auto-immune condition if a risk assessment with their primary health care provider or medical specialist determines that the benefits outweigh the potential risks. Risks would include that: <ul style="list-style-type: none"> ➤ Immunocompromised persons may have a diminished immune response to the vaccine and ➤ There is a theoretical concern that mRNA vaccine may elicit an inflammatory response and possibly exacerbate existing autoimmune diseases. However, current applications of mRNA technology for COVID-19 vaccines have been optimized to reduce this risk.² With the exception of SOT and HSCT clients, the individual may be immunized without consulting their primary health care provider or medical specialist following their acknowledgment in writing of the risks mentioned above and the absence of evidence on the use of COVID-19 vaccine in these populations. Refer to the COVID-19 Vaccine Precautions, Recommendations and Scripts document and ensure that the appropriate Benefit/Risk Information form is signed by the client.
Pregnancy	<ul style="list-style-type: none"> The safety and efficacy of Moderna COVID-19 Vaccine in pregnant women have not yet been established. There is a pregnancy exposure registry that monitors pregnancy outcomes in women exposed to Moderna COVID-19 Vaccine during pregnancy. Women who are vaccinated with Moderna COVID-19 Vaccine during pregnancy are encouraged to enroll in the registry by calling 1-866-MODERNA (1-866-663-3762). At this time, as there is an absence of evidence on the use of COVID-19 vaccine in pregnant individuals. Pregnant individuals were excluded from the mRNA COVID-19 vaccine clinical trials <p>COVID-19 vaccine may be offered to individuals in the eligible group who are pregnant if a risk assessment with their primary health care provider or Obstetrician determines that the benefits outweigh the potential risks for the woman and fetus.</p> <ul style="list-style-type: none"> However, the individual may also be immunized without consulting their primary health care provider or medical specialist following their acknowledgment in writing of the absence of evidence on the use of COVID-19 vaccine in this population. It would be prudent to delay pregnancy by 28 days or more after the administration of the complete two-dose vaccine series of an mRNA COVID-19 Vaccine. Refer to the COVID-19 Vaccine Precautions, Recommendations and Scripts document and ensure that the appropriate Benefit/Risk Information form is signed by the client.
Lactation	<ul style="list-style-type: none"> It is unknown whether Moderna Vaccine is excreted in human milk. A risk to the newborns/infants cannot be excluded. At this time, there is an absence of evidence on the use of COVID-19 vaccine in breast feeding individuals. These groups were not included in the initial trials to provide solid information.

	<ul style="list-style-type: none"> COVID-19 vaccine may be offered to individuals in the eligible group who are breastfeeding if a risk assessment with their primary health care provider determines that the benefits outweigh the potential risks for the mother and infant. However, the individual may also be immunized without consulting their primary health care provider or medical specialist following their acknowledgment in writing of the absence of evidence on the use of COVID-19 vaccine in this population. Refer to the COVID-19 Vaccine Precautions, Recommendations and Scripts document and ensure that the appropriate Benefit/Risk Information form is signed by the client.
Other considerations	<ul style="list-style-type: none"> Individuals with a history of lab confirmed COVID-19 infection who have no contraindications can be provided COVID-19 vaccine. Individuals presenting for immunization do not need to be tested for previous COVID-19 infection. Immunization of individuals who may be currently infected with SARS-CoV-2 is not known to have a detrimental effect on the illness. However, individuals with COVID-19-like symptoms should not go to an immunization/venue in order to minimize the risk of COVID-19 transmission and their immunization should be deferred. For residents of LTCFs/PCHs who are isolated due to COVID-19-like symptoms, immunization should be deferred until the test result is back and negative and the person is otherwise eligible based on the acuity of their symptoms (i.e. no acute severe febrile illness).
Possible reactions	<p>Common or very common</p> <ul style="list-style-type: none"> Pain at the injection site Redness or swelling at injection site, vomiting, diarrhea Chills or fever Fatigue Headache, myalgia, arthralgia Nausea, vomiting Lymphadenopathy <p>Rare</p> <ul style="list-style-type: none"> Facial swelling Anaphylaxis
Interchangeability	<ul style="list-style-type: none"> Currently, no data exists on the interchangeability of COVID-19 vaccines. The vaccine series should be completed with the same COVID-19 vaccine product. If the vaccine product used for a previously received dose is not known, or not available, attempts should be made to complete the vaccine series with a similar type of COVID-19 vaccine (e.g. mRNA vaccine). The previous dose may be counted, and the series need not be restarted.
Administration with Other Products	<ul style="list-style-type: none"> In the absence of evidence, COVID-19 vaccines should not be given simultaneously with other live or inactivated vaccines due to the potential for immune interference and the need to be able to monitor for potential symptoms of COVID-19 and COVID-19 vaccine adverse events without potential confounding from adverse events following other vaccines. If a COVID-19 vaccine is inadvertently administered at the same time as another vaccine, neither dose should be repeated.

	<ul style="list-style-type: none"> In the absence of evidence, it would be prudent to wait for a period of at least 28 days between the administration of the complete two-dose schedule of COVID-19 vaccine and the administration of another vaccine (except in the case where another vaccine is required for post-exposure prophylaxis). In the absence of evidence, it would be prudent to wait for a period of at least 14 days after the administration of another vaccine before administering a COVID-19 vaccine.
Appearance	<ul style="list-style-type: none"> Frozen and thawed - white to off-white and may contain white or translucent particles.
Storage and Handling	<ul style="list-style-type: none"> No reconstitution is required. Do not store on dry ice or below -40°C (-40°F). Can be stored in a freezer between -25°C and -15 °C.^{1\} <p>Vaccine can be thawed in two ways:</p> <ul style="list-style-type: none"> From the freezer to room temperature (between +15°C to +25°C), thaw for 1 hour from frozen state. From the freezer to a vaccine fridge +2°C to +8°C; thaw for 2 hours and 30 minutes from frozen state. Let the vial stand at room temperature for 15 minutes before administering. Do not refreeze after thawing. Swirl vial gently after thawing and between each withdrawal. Do not shake. <p>Thawed, unpunctured vials</p> <ul style="list-style-type: none"> Thawed, unpunctured vials can be stored at +2°C to +8°C up to 30 days, Thawed, unpunctured vials may be stored at +8°C to +25°C for up to 12 hours. <p>Thawed, punctured vials</p> <ul style="list-style-type: none"> Thawed, punctured vials (first dose is withdrawn) can be stored at +2°C to +25°C for 6 hours. Discard after six hours.
Packaging	<ul style="list-style-type: none"> 10 doses per vial 100 doses per box Box 51 mm long x 126 mm wide x 60 mm high 12 boxes/carton (1200 doses/carton) Carton 267 mm long x 169 mm wide x 135 mm high
Ingredients	<p>Lipid nanoparticles (these help the mRNA enter the cell)</p> <ul style="list-style-type: none"> PEG2000-DMG LSM-102, 1,2-dimyristoyl-rac-glycero-3-methoxy-polyethyleneglycol 1,2-distearoyl-sn-glycero-3-phosphocholine [DSPC] Cholesterol Lipid SM-102 <p>pH stabilizers (help maintain the pH of the vaccine)</p> <ul style="list-style-type: none"> acetic acid sodium acetate tromethamine tromethamine hydrochloride <p>Other</p> <ul style="list-style-type: none"> sucrose (protects the nanoparticles when frozen)
Preparation/ Reconstitution	<p>The Moderna COVID-19 Vaccine multiple dose vial contains a frozen suspension that does not contain preservative and must be thawed prior to administration.</p> <p>Thaw vaccine before use:</p> <p>The frozen vial contains 5 mL and will need to be thawed before use.</p>

	<ul style="list-style-type: none"> • Vials may be thawed in the refrigerator (+2°C to +8°C) or at room temperature (up to +25°C). <ul style="list-style-type: none"> ➤ thaw for 2.5 hour at room temperature. ➤ thaw for 2.5 hours in the refrigerator; and ➤ allow the vial to come to room temperature before administration. <p>Using vaccine contents from more than 1 vial to make a complete dose is not acceptable practice for vaccine preparation or administration.</p> <p>Notes: Pre-loading vaccine into syringes is not a recommended practice. The immunizing health practitioner should draw up each vaccine dose at the time of administration.</p>
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References

- Moderna (2020 December 23). Moderna COVID-19 Vaccine mRNA-1273 SARS-CoV-2 vaccine, suspension for intramuscular injection: *Product Monograph*. <https://covid-vaccine.canada.ca/info/pdf/moderna-covid-19-vaccine-pm1.pdf>
- National Advisory Committee on Immunization. (2020/2021). Recommendations on the use of COVID-19 Vaccines.
- Health Canada. Recalls and safety alerts. (2020 December 12) Pfizer-BioNTech COVID-19 vaccine: Health Canada recommendations for people with serious allergies. <https://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2020/74543a-eng.ph>
- Moderna Training Resources. December 29, 2020.